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Hiroyuki Morimoto

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EXAMINER

TRAN, SUSAN T

ART UNIT

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1615

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Response to Arguments

Applicant's arguments filed 10/08/08 have been fully considered but they are not persuasive.

Applicant argues that Tsushima relates to a disparate process of producing an aqueous molding tablet by compressing wet material in a mold, removing a wet tablet from the mold after compression and drying the tablet. Moreover, Tsushima applies lubricant directly to the paste surfaces, not to the punch and die. Additionally, Applicants explained why Tsushima cannot be combined with Roche anyway. For all these reasons, it was respectfully thought that the rejection was addressed, since Morimoto does not remedy these failings. However, it is further seen from the following that any *prima facie* case of obviousness is, in any event, rebutted by the showings of unexpected improvements over the prior art. That is, the data of record illustrates conclusively that, when stearic acid is included in the molding material as in the prior art, tablets with inferior hardness are obtained when the molding material is compressed at Applicants' tableting pressure of 0.7 to 1.3 ton/cm². This data is summarized and explained below to complete the record.

In response to applicant's arguments, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Tsushima is cited solely for the teaching

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of stearic acid and stearic acid metal salt as lubricant, is well known lubricant in pharmaceutical art. The claimed process is however, clearly taught by Morimoto, namely, spring lubricant uniformly on the surface of an upper punch, lower punch, and a die.

/S. Tran/
Primary Examiner, Art Unit 1615